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TITLE: Improved Training Program for Fall Prevention of Warfighters with Lower Extremity Trauma

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14. ABSTRACT Overseas Contingency Operations have produced many U.S. warfighters with lower extremity injuries. Although the U.S. military has access to state-of-the-art treatment and devices, warfighters with extremity trauma still struggle to regain full functional capabilities. A key factor that limits the ability of individuals with lower extremity trauma to achieve maximum functional capabilities is falls. Falls have serious consequences including loss of confidence, fear of falling, and injury. Warfighters with lower extremity trauma need to face the risk of falling and overcome that fear. After standard rehabilitation for amputation or limb salvage, many warfighters still struggle with falls, which can exacerbate physical and emotional injury and delay healing. When individuals trip or slip, they are still likely to fall and injure themselves, in spite of advances in rehabilitation care. The proposed project develops a secondary rehabilitation program, implemented after traditional therapy, and designed to reduce falls in warfighters with amputations or salvaged limbs. The goals of this research effort are to augment existing rehabilitation with a novel, demonstrably successful fall-prevention training method to help warfighters return to full high-level functional capabilities and emotional wellness, and to decrease the time required to either return to active duty or to a productive, active civilian life. The training program utilizes a microprocessor-controlled treadmill designed to deliver task-specific training perturbations. The training consists of six, 30 minute sessions delivered over a 4-week period. In the second year, we have validated the performance of a low cost motion measurement system to quantify trunk kinematics and obtained HRPO approval to begin data collection.					
15. SUBJECT TERMS Amputation, Limb Salvage, Falls, Fall Prevention, Rehabilitation, Therapy					
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1. INTRODUCTION

After standard rehabilitation for amputation or limb salvage, many warfighters still struggle with falls, which can exacerbate physical and emotional injury and delay return to active duty or to a productive, active civilian life. Following a trip or slip, many warfighters are still likely to fall and injure themselves, in spite of advances in rehabilitation care. Adaptations due to the loss of function, while necessary, may also limit physical performance and reduce quality of life. The proposed project describes a secondary rehabilitation program, implemented after and as augmentation to existing rehabilitation by providing advanced fall-prevention training, to help warfighters return to as close to full high-level functional capabilities and emotional wellness as possible, and to decrease the time required to either return to active duty or to a productive, active civilian life. The proposed novel training method has the potential to change the standard of care for lower extremity limb trauma.

2. **KEYWORDS:** Amputation, Limb Salvage, Falls, Fall Prevention, Rehabilitation, Therapy,

3. ACCOMPLISHMENTS

- **What were the major goals of the project?**

Our study has three main objectives, which will be achieved over a three-year timeframe. First, we will implement a novel postural perturbation training program in the three DOD Medical Treatment facilities. This rehabilitation protocol will be provided to active-duty service members who have suffered combat-related lower limb trauma, specifically amputations or salvaged limbs. Second, we will assess whether the benefits of improved motor skills induced by the rehabilitation protocols can be retained following training. Third, we will identify, evaluate, and implement existing low cost methods for measuring trunk control that can be used in lieu of substantially more expensive fixed motion capture systems. This will ensure that the rehabilitation program can be transitioned to clinical settings.

- **What was accomplished under these goals?**

The primary goals in the second year of the study were to enhance project infrastructure and obtain regulatory review of the study protocol.

Major activities:

- The fall prevention training program utilizes a microprocessor-controlled treadmill to deliver task specific training perturbations. The computer software has been delivered to provide these disturbances for the treadmill at NMCS D. A User's Guide has also been produced for this software. Treadmills are currently being installed at CFI and WRNMMC. Work has begun to provide the programming needed to operate these additional treadmills. This equipment is central to the perturbation training program.
- The key outcome variables are peak trunk flexion and trunk velocity between the time of treadmill perturbation onset and recovery step completion. These variables have been shown to determine the likelihood of a fall. A low cost method for measuring trunk control has been identified. This method uses an inertial measurement unit (IMU) (Opal, APDM, Portland, OR). The accuracy and precision of these devices has been established from a set of 8 sensors. For both the large and small angular displacement testing; the average sensor output accuracy (Fig. 1a & 1b) was within 0.6 ± 0.1 degrees of the true value. The sensors had equal precision on the static apparatuses with average precision of 0.1 ± 0.1 degrees (Fig. 1c & 1d). An increase in angular velocity resulted in an increase in the difference between the testing device input and

IMU output. The average percent error for a dynamic trial of a sensor was less than 1.5 dps. The dynamic testing average accuracy was 4.4 ± 0.2 dps (Fig. 2e) and precision was 0.2 ± 0.3 dps (Fig. 2f).

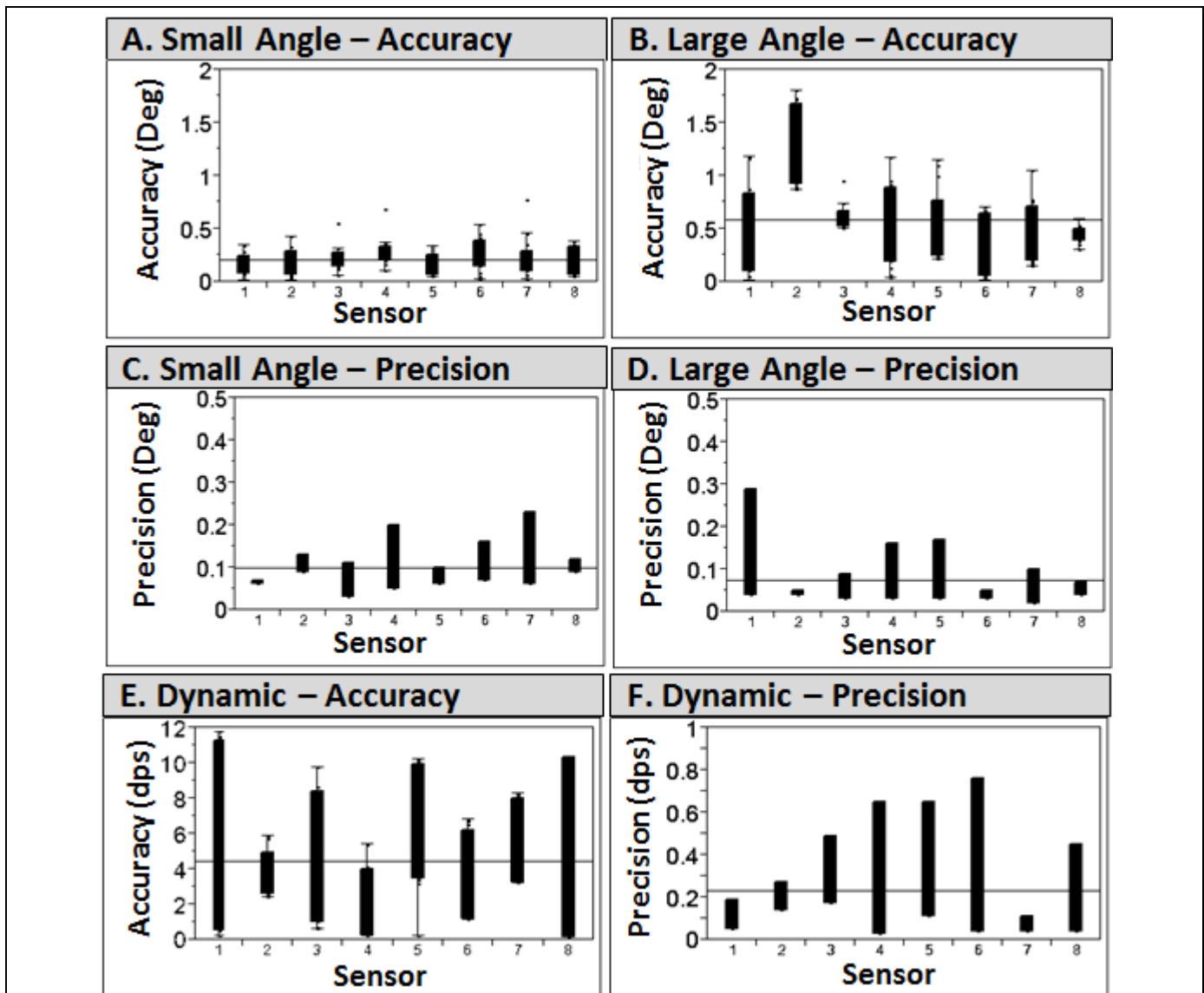


Figure 1: Box plots of IMU (A) small angle static accuracy, (B) large angle static accuracy, (C) small angle static precision, (D) large angle precision, (E) dynamic velocity accuracy, and (F) dynamic velocity precision. The central line represents the median, the edges of the box are the 25th and 75th percentiles, and the whiskers extend to ± 1.5 of the interquartile range.

- The research program has two study protocols. The first protocol was a comparison of IMU sensors to motion capture for measuring trunk motion and velocity during treadmill disturbance activities. Ten subjects (5F; 30 ± 6 yrs; 24 ± 2 BMI) participated in the study. The subjects donned reflective markers, an IMU positioned on the trunk, and a safety vest. Subjects were instructed to stand in the middle of the treadmill, where they were attached to a harness mounted in the ceiling. The harness was adjusted to give the subjects enough room to recover from a fall but enough security to not completely fall to the ground. The subjects were provided both forward and backward disturbances. When the subject successfully recovered for a given disturbance, the magnitude of the disturbance was increased. The subject failed when they experienced a fall. The trial was considered a fall when the harness obviously provided

substantial support to the falling subject. A subject's testing was complete when the subject fell three times in both the forward and backward directions. All data collection on this test protocol has been completed. The data is currently being analyzed.

The testing was repeated for a second harness condition. The two harness conditions consisted of the harness either being fixed in one location or being allowed to move on a trolley connected to a rail. This was performed in order to determine if differences in harness setups between the participating sites would have an effect on measurement outcomes. The order of forward and backward disturbances and the harness condition was randomized for all subjects. There was no difference in trunk kinematics for the fixed vs moveable harness attachment for all test conditions ($p>0.30$) (Figure 2).

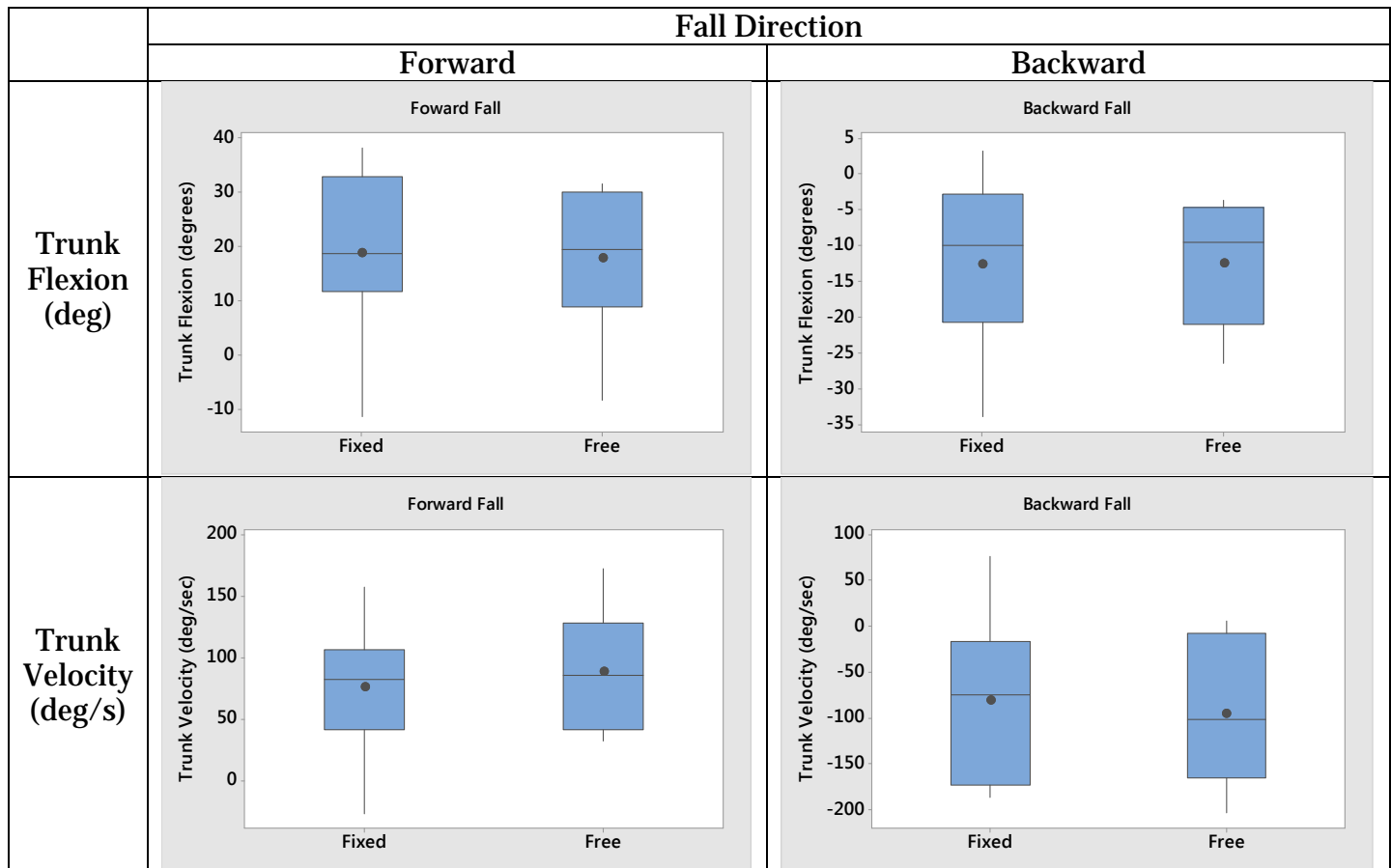


Figure 2. Comparison of trunk kinematics when using a fixed vs free attachment point for the safety harness. There are no significant difference ($p>0.3$) in trunk kinematics for the different harness methods.

The second protocol is to assess the extent to which the novel fall-prevention training program reduces falls and fall-risk and enhances acquisition of functional capabilities for patients with lower extremity trauma. This protocol has been reviewed and approved by the IRBs and HRPO. Data collection will commence shortly.

- **What opportunities for training and professional development has the project provided?**

Nothing to report.

- **How were the results disseminated to communities of interest?**

The IMU validity study was presented at the 2017 annual meeting of the American Society of Biomechanics held in Boulder Colorado.

- **What do you plan to do during the next reporting period to accomplish the goals?**

- The postural perturbation software will be modified for the treadmills at CFI and WRNMMC.
- Study staff will be hired and trained on operation of the treadmill system.
- Subject recruitment and enrollment will commence for the second protocol.
- A paper will be submitted on the comparison of the IMU vs motion capture for quantifying trunk kinematics.

4. IMPACT

- **What was the impact of the development of the principal discipline(s) of the project?**

Nothing to report.

- **What was the impact on other disciplines?**

Nothing to report.

- **What was the impact on technology transfer?**

Nothing to report.

- **What was the impact on society beyond science and technology?**

Nothing to report.

5. CHANGES/PROBLEMS

- **Changes in approach and reasons for change**

No changes to report.

- **Actual or anticipated problems or delays and actions or plans to resolve them**

There were significant delays in HRPO approval that delayed the start of the second protocol. Approval for the second project was received on August 17, 2017.

- **Changes that had a significant impact on expenditures**

Nothing to report.

- **Significant changes in use or care of human subjects**

None.

6. PRODUCTS

- **Publications, conference papers, and presentations**

Journal Publication: Taylor L, Miller E, Kaufman KR. Static and dynamic validation of inertial measurement units. *Gait & Posture*, 57:80-84, 2017.

Abstract: *Taylor L, Miller E, Kaufman KR. Validation of inertial measurement units. 41st annual meeting of the American Society of Biomechanics, Boulder, Colorado, August 8-11, 2017.

- **Website(s) or other Internet site(s)**
Nothing to report.
- **Technologies or techniques**
Nothing to report.
- **Inventions, patent applications, and /or licenses**
Nothing to report.
- **Other products**
Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name:	Kenton Kaufman, PhD, PE
Project Role:	Principal Investigator, Mayo Clinic
Nearest person month worked:	3
Contribution to Project:	Dr. Kaufman held regular meetings with the Co-Investigators. He has prepared materials for submission to the Mayo IRB and HRPO. He has worked to develop the standard operating procedures for the research protocols. He has served as the liaison with the Grants Officer's Representative and has provided the required quarterly and annual reports.
Funding Support:	

Name:	Leah Taylor, MS
Project Role:	Research Engineer, Mayo Clinic
Nearest person month worked:	5
Contribution to Project:	Leah Taylor attended regular meetings with the Co-Investigators. She worked on the static and dynamic Inertial Measurement Unit (IMU) validation. A paper on this work has been published and results presented at the 2017 American Society of Biomechanics.
Funding Support:	

Name:	Emily Miller, MS
Project Role:	Research Engineer, Mayo Clinic
Nearest person month worked:	4
Contribution to Project:	Emily Miller attended regular meetings with the Co-Investigators. She has conducted tests to validate the trunk kinematics from the IMUs vs motion capture. She has developed custom software to implement the controlled disturbances on the AMTI treadmill utilized in the training program and written a user's manual.
Funding Support:	

Name:	Christine Huyber, CCRP
Project Role:	Kinesiologist, Mayo Clinic

Nearest person month worked:	2
Contribution to Project:	Christine Huyber attended regular meetings with the Co-Investigators. She has developed surveys for subjects in the study and REDCap data collections tools for use across institutions.
Funding Support:	

Name:	Marilynn Wyatt, MA, PT
Project Role:	Site Principal Investigator, NMCSO
Nearest person month worked:	1
Contribution to Project:	Ms. Wyatt is the NMCSO site principal investigator for the project. She has attended all study meetings with the other Co-Investigators and coordinates the work being accomplished at Naval Medical Center San Diego (NMCSO). The focus this year continued to be on the multi-site IRB approvals and secondary approval of HRPO. NMCSO is the IRB of record for the three DoD study sites. HRPO approval has been received this last quarter and preparations for subject enrollment are underway. She supervises the engineering work taking place on the instrumented treadmill which involved installation and testing of the perturbation profiles on the AMTI treadmill, the IMU testing and the trunk postural control assessment device, and research protocol. She has worked with Geneva Foundation to coordinate the sub-award requirements and hiring is ongoing.
Funding Support:	Federal Employee

Name:	Tatiana Djafar, MA
Project Role:	Engineer, NMCSO
Nearest person month worked:	1
Contribution to Project:	Ms. Djafar is the NMCSO site engineer for the project. Her role is to oversee the technical aspects of the project for NMCSO and support the other sites as required. She has continued programmed the AMTI instrumented treadmill to deliver the perturbation tasks. This has involved troubleshooting and fine-tuning the software and controlled disturbances. The perturbation profiles are working.
Funding Support:	

Name:	Pinata Sessoms, PhD
Project Role:	Site Principal Investigator, Naval Health Research Center
Nearest person month worked:	1
Contribution to Project:	Dr. Sessoms is the NHRC site lead for the project. Dr. Sessoms has worked in conjunction with Ms. Wyatt to complete the CRADA between the Navy, Mayo Clinic, and Geneva Foundation. During the current reporting period, Dr. Sessoms has participated in the regularly scheduled meetings with Co-Investigators and has served as liason to key personnel at NHRC, helping to obtain the needed approvals

	from NHRC personnel for the multi-site IRB protocol.
Funding Support:	BUMED

Name:	John Fergason
Project Role:	Site Principal Investigator, Center for the Intrepid, Brooke Army Medical Center
Nearest person month worked:	2
Contribution to Project:	John Fergason has participated in regular teleconferences with CO-Investigators.
Funding Support:	Federal Employee

Name:	Riley C. Sheehan, PhD
Project Role:	Site Principal Investigator, Center for the Intrepid, Brooke Army Medical Center
Nearest person month worked:	3
Contribution to Project:	Riley Sheehan has participated in regular teleconferences with CO-Investigators as well as attended the project meeting held at the American Society of Biomechanics annual meeting. He has also coordinated the administration of the Henry Jackson Foundation sub-award to the CFI.
Funding Support:	Henry M. Jackson Foundation Sub-award

Name:	Noel Guerrero
Project Role:	Research Assistant, Center for the Intrepid, Brooke Army Medical Center
Nearest person month worked:	3
Contribution to Project:	Noel Guerrero has participated in regular teleconferences with CO-Investigators. He has also worked to prepare equipment for data collection including instructions for initializing the IMU's.
Funding Support:	Henry M. Jackson Foundation Sub-award

Name:	Mark D. Grabiner, PhD
Project Role:	Site Principal Investigator, University of Illinois-Chicago
Nearest person month worked:	2
Contribution to Project:	Dr. Grabiner attended the regularly scheduled meetings with the research team. He directs and oversees the effort of a 0.25 FTE doctoral student on this project. The project-based work at UIC is focused on post-collection analysis of biomechanical data collected at and transferred from Mayo, NMCSO, CFI, and WRNMMC.
Funding Support:	

Name:	Christopher L. Dearth, PhD
Project Role:	Site Principal Investigator, Walter Reed National Military Medical Center
Nearest person month worked:	1
Contribution to Project:	During the current reporting period, Dr. Dearth has participated in all study meetings, coordinated equipment

	orders/deliveries/install and personnel hiring actions, and engaged in discussions with WRNMMC clinical and research staff to ensure a smooth start to subject enrollment and data collection in the upcoming year.
Funding Support:	Federal Employee

Name:	Bradford D. Hendershot, PhD
Project Role:	Associate Investigator, Walter Reed National Military Medical Center
Nearest person month worked:	1
Contribution to Project:	During the current reporting period, Dr. Hendershot has participated in all study meetings, assisted with the coordination of equipment orders/deliveries/install and personnel hiring actions, and engaged in discussions with WRNMMC clinical and research staff to ensure a smooth start to subject enrollment and data collection in the upcoming year. He has also led the development and validation of a trunk postural control assessment device and testing protocol, to be used at all sites.
Funding Support:	Federal Employee

Name:	Elizabeth Husson, CCRC
Project Role:	Associate Investigator, Walter Reed National Military Medical Center
Nearest person month worked:	1
Contribution to Project:	During the current reporting period, Ms. Husson has participated in all study meetings, assisted with the coordination of equipment orders/deliveries/install and personnel hiring actions and assisted with the creation of documentation for the clinical research protocol that was submitted to the NMCSO IRB and HRPO
Funding Support:	Federal Employee

Name:	Jason Wilken, PT, PhD
Project Role:	Collaborator, University of Iowa
Nearest person month worked:	1
Contribution to Project:	Dr. Wilken previously was the Site Principal Investigator at CFI. He participated in all regularly scheduled meetings. He supervised treadmill acquisition and worked on obtaining regulatory approval. He is now at the University of Iowa. He will continue to participate in regularly scheduled meetings. He will also participate in data analysis and reporting results from the study.
Funding Support:	

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
No.

- **What other organizations were involved as partners?**

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

- **Collaborative Awards**

- **Quad Chart**

9. APPENDICES